REMARKS

Claims 1 and 3-17 are currently pending in this application. Upon entry of these amendments, claims 1, 4-15, and 18-19 will be pending.

<u>Amendments</u>

No new matter is introduced into the specification through entry of new claims 18 and 19, and support for new claims 18 and 19 can be found in the specification as originally filed. More specifically, new claim 18 finds support, *inter alia*, in the specification in Example 4. New claim 19 finds support, *inter alia*, in the specification and in originally filed claim 10. Amended claim 1 finds support, *inter alia*, in the specification as originally filed on page 1, lines 3-4, and page 6, lines 23-31. Amended claim 14 finds support, *inter alia*, in the specification as originally filed on page 6, lines 23-31, on page 7 lines 22-25, and on page 11, lines 8-16. Amended claim 15 finds support, *inter alia*, in the specification as originally filed on page 6, lines 23-31, and on page 8 lines 5-24.

<u>Objections</u>

The Examiner objected to claim 10 as being in improper form "because a multiple dependent claim cannot depend from a claim which is dependent on another multiply dependent claim." *See* Paper No. 19, page 4, lines 11-13.

Applicants have amended claim 10 to remove the improper multiple dependency. Applicants respectfully request reconsideration and withdrawal of the objection to claim 10 as being in improper form.

<u>Rejections</u>

Rejections under 35 U.S.C. § 112, 1st Paragraph

Claim 14 stands rejected under 35 U.S.C. § 112, 1st paragraph, as allegedly "containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention". *See* Paper No. 19, page 3, lines 3-6. The Examiner further stated that it is "noted that the porcine KIT protein has at least 19 exons, whereas the specification has only taught a single splice variant (a protein lacking exon 17) and has only

correlated white coat color with said single splice variant. The specification fails to describe a representative number of the various splice variants encompassed by the claims, such as proteins lacking a single or multiple exons, and further fails to demonstrate an association between these numerous undisclosed splice variants and white coat color in a pig." *See* Paper No. 19, page 3, lines 13-18.

Applicants have amended claim 14 to more distinctly recite the subject matter sought to be claimed, and have rendered moot the basis of the Examiner's rejection of claim 14 under 35 U.S.C. § 112, 1st paragraph. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection of claim 14 under 35 U.S.C. § 112, 1st paragraph in light of the claim amendments filed herein.

Claims 1 and 3-17 stand rejected under 35 U.S.C. § 112, 1st paragraph, as allegedly failing to "reasonably provide enablement for a method for determining coat color genotype in a pig by determining whether 1) any mutation is present at exon 17/intron 17 boundary of KIT gene, wherein presence or absence of the mutation is correlated with coat color or 2) any splice variant protein present being correlated with coat color". *See* Paper No. 19, page 6, lines 14-18. The Examiner further asserted that "[t]he single mutation which leads to the single splice variant protein lacking exon 17 taught by the specification is not sufficient to establish a predictable correlation for the skilled artisan between the large number of mutations that might result in an altered exon 17...or splice variant proteins encompassed by the claims and white coat color of a pig." *See* Paper No. 19, page 9, lines 6-10. Applicants appreciate the Examiner's acknowledgment that the specification teaches one mutation, which leads to a single specific splice variant protein, and when present, is correlated with white coat color." *See* Paper No. 9, page 10, lines 7-9.

Applicants have amended claims 1, 14 and 15 to more distinctly recite the subject matter sought to be claimed, and have rendered moot the basis for the Examiner's rejection of claims 1 and 3-17 under 35 U.S.C. § 112, 1st paragraph. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 1 and 3-17 under 35 U.S.C. § 112, 1st Paragraph in light of the claim amendments filed herein.

Rejections under 35 U.S.C. § 112, 2nd Paragraph

Claims 1 and 3-17 stand rejected under 35 U.S.C. § 112, 2nd paragraph, as allegedly "being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention." *See* Paper No. 19, page 4, lines 16-18. More specifically, the Examiner asserted that "[c]laims 1 and 15 are indefinite in the recitation of 'presence or absence of said mutation is correlated with white coat color' because it is unclear how the presence and absence of mutation can be correlated with white color." *See* Paper No. 19, page 5, lines 1-3. The Examiner additionally rejected claims 1 and 15 under 35 U.S.C. § 112, 2nd paragraph, as allegedly failing to relate the last process step back to the preamble which states 'a method for determining whether a pig has a white coat color.'

Applicants have amended claims 1 and 15 to more distinctly recite the subject matter sought to be claimed, thereby rendering moot the basis of the Examiner's rejection of claims 1 and 3-17 under 35 U.S.C. § 112, 2nd paragraph. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 1 and 15 under 35 U.S.C. § 112, 2nd paragraph in light of the claim amendments filed herein.

Claim 14 stands rejected under 35 U.S.C. § 112, 2nd Paragraph as allegedly lacking sufficient antecedent basis for the recitations of "the splice variant protein" and "said protein".

Applicants have amended claim 14 to clarify the language giving rise to the antecedent basis rejection, thereby rendering the Examiner's rejection of claim 14 moot. Applicants respectfully request reconsideration and withdrawal of the rejection of claim 14 under 35 U.S.C. § 112, 2nd Paragraph in light of the claim amendments filed herein.

Rejections under 35 U.S.C. § 102

Claim 15 stands rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by the New England Biolabs 1996 catalog.

Applicants have amended claim 15 to more distinctly recite the subject matter sought to be claimed, and have rendered moot the grounds of the Examiner's rejection of claim 15 under 35 U.S.C. § 102 (b). Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection of claim 15 under 35 U.S.C. § 102(b) in light of the claim amendments filed herein.

Rejections under 35 U.S.C. § 103

Claims 15 and 16 stand rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Moller *et al.* in view of Ohler *et al.*, and further in view of Ahern *et al.*

Applicants have cancelled claim 16 herein, and have amended claim 15 to incorporate limitations contained within cancelled claims 16 and 17. Applicants assert that claim 15, as amended, is not obvious in light of the Moller *et al.*, Ohler *et al.* and Ahern *et al.* references. Applicants respectfully request reconsideration and withdrawal of the rejection of claims 15 and 16 under 35 U.S.C. § 103(a) as allegedly unpatentable over Moller *et al.* in view of Ohler *et al.*, and further in view of Ahern *et al.*

Conclusion

Applicants believe that incorporation of the amendments and consideration of the above remarks have placed this application in a condition for allowance. Early notification of a favorable consideration is respectfully requested.
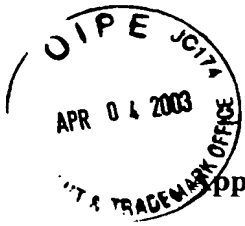
Respectfully submitted,

HUNTON & WILLIAMS LLP

Dated: <u>April 4, 2003</u>   By: _____

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application Number: 09/550,605   **Examiner:** Souaya, J.E.

Filing Date: April 17, 2000   **Art Unit:** 1634

Title: Methods for Determining Coat Colour   **Inventor:** Andersson, L., *et al.*.
Genotypes in Pigs

Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office

Washington, D.C. 20231

Appendix A – Version with Markings to Show Changes Made to the Specification

Claim 1:

--1 (Thrice amended). A method for determining ~~whether a pig has a white coat color~~ ~~comprising~~ <u>coat colour genotype in a pig which comprises</u>:

    (a) obtaining a sample of pig nucleic acid; and

    (b) analysing the nucleic acid obtained in (a) to determine whether a mutation is/is not present at an exon 17/intron <u>17</u> splice site of <u>a</u> KIT gene, wherein ~~presence or absence of said mutation is correlated with white coat color~~ <u>the mutation consists of the substitution of the G in the conserved GT pair by A</u>.--

Claim 10:

--10. (Twice Amended) The method according to claim 8 ~~or claim 9~~, wherein the ratio of restriction fragment lengths is determined.--

Claim 14:

--14. (Thrice amended). A method for determining ~~whether a pig has a white coat color~~ ~~comprising~~ <u>coat colour genotype in a pig which comprises</u> the step of analysing a sample of pig KIT protein to determine whether the protein is ~~the~~ <u>a</u> splice variant protein~~, said protein being correlated with white coat color~~ <u>produced by the substitution of G in the conserved GT pair by A, at an exon 17/intron 17 splice site of a KIT gene, said splice variant protein being correlated with coat colour genotype</u>.--

Claim 15:

--15. (Thrice amended). A kit for use in determining ~~whether a pig has a white coat color comprising~~ the coat colour genotype of a pig which comprises one or more reagents ~~suitable for determining whether a mutation is present at an exon 17/intron 17 splice site of the KIT gene, wherein presence or absence of the mutation is correlated with white coat color~~ for carrying out PCR and the following pair of primers:

5'-GTA TTC ACA GAG ACT TGG CGG C-3' (SEQ ID NO:1);
5'-AAA CCT GCA AGG AAA ATC CTT CAC GG-3' (SEQ ID NO:2).--